

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
44657-AAA-PCT-USSerial No.
10/052,961INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)Applicant:
Joseph R. BergerFiling Date
January 18, 2002

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
SW	US 3 1 2 8 2 8 3	4/7/64	Pappo			
SW	US 5 4 6 1 0 3 0	10/24/95	Lindenbaum			
SW	US 5 5 3 2 2 3 0	7/2/96	Daynes			
SW	US 5 9 2 2 7 0 1	7/13/99	Araneo			
SW	US 6 8 2 8 3 1 3	12/7/04	Fishbein			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
					Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SW	Protest Under 37 C.F.R. §1.291(a) filed on October 18, 1999 with the United States Patent and Trademark Office in connection with U.S. Serial No. 08/244,988, pp. 1-7, including a cover sheet, a Form PTO-1449, and Exhibits A-E
	March 2, 2000 Decision on Protest Under 37 C.F.R. §1.291(a) in connection with U.S. Serial No. 08/244,988, pp. 1-2, including a cover sheet, a Form PTO-892, Information on Submitting an INDA (2 pages), and a copy of 21 C.F.R. 312 (39 Pages)
	May 14, 1999 letter from the Department of Health and Human Services, Center For Drug Evaluation and Research, Rockville, Maryland, providing a "Copy of All Disclosable Approval Information For the Product Oxandrin, Manufactured by Biotechnology General," 30 pages
	Albanese, A.A., Lorenze, E.J., and Orto, L.A., (May 15, 1962) Nutritional and Metabolic Effects of Some Newer Steroids, Oxandrolone and Triamcinolone, New York State J. Med. 62:1607-1613
	Albanese et al., (1970), "Steroid and Dietary Effects On Blood Lipids In Elderly Persons," Nutrition Reports International, Vol. 1, No. 4, pp. 231-242
	Bailey, R.O., Turok, D.I., Jauffmann and Singh, J.K. (1987). Myositis and acquired immunodeficiency syndrome. Hum. Path. 18:749-751
	Berger, J.R., (1991). Personal communication between Dr. Berger and Dr. Dudley of Gynex (letter dated July 6, 1991)
	Berkowitz, D., Clinical Investigator's Report, April 25, 1962
	Bessen, L.J., Greene, J.B., Louie, E., Seitzman, P., and Weinberg, H. (1988). Severe polymyositis-like syndrome associated with zidovudine therapy in AIDS and ARC. N. Eng. J. Med. 318:708
	Blizzard, R.M., Hindmarsh, P.C. and Stanhope, R. (1991). Oxandrolone therapy: 25 years experience. Growth, Genet. Hor. 7:1-7
	Chelbowski, R.T., Grosvenor, M.B., Bernhard, N.H., Morales, L.S. and Bulcavage, L.M. (1989). Nutritional status, gastrointestinal dysfunction and survival in patients with AIDS. Am. J. Gastroent. 84:1288-1293
	Chernoff, D. (1990). Myositis in HIV-infected patients. In the AIDS Knowledge Base, Cohen, P.T., Sande, M.A. and Volberding, P.A. (eds.). Waltham, The Medical Publishing Group, pp. 5.14. 1-2
	Dalakas, M.C., Pezeshkpour, G.H., Gravell, M. and Sever, J.L. (1986). Polymyositis associated with AIDS retrovirus. J. Amer. Med. Assoc. 256:2381-2383
	Demling et al., (1996), "Use of Anticatabolic Agents For Burns," Current Opinion in Critical Care, Vol. 2, pp. 482-491
SW	Demling, (1999), "Comparison of the Anabolic Effects and Complications of Human Growth Hormone and the Testosterone Analog, Oxandrolone, After Severe Burn Injury," Burns, Vol. 25, pp. 215-221

EXAMINER

S. Wang

DATE CONSIDERED

1/3/06

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant: Joseph R. Berger
U.S. Serial No.: 10/052,961
Filed: January 18, 2002
Exhibit A

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
44657-AAA-PCT-USSerial No.
10/052,961INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)Applicant:
Joseph R. BergerFiling Date
January 18, 2002

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
					Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SW	Demling and DeSanti, (2001), "The Rate of Restoration of Body Weight After Burn Injury, Using the Anabolic Agent Oxandrolone, is not Age Dependent," Burns, Vol. 17, pp. 46-51
	Draft of G.D. Searle & Co., (1962), Physicians' Product Brochure No. 43, "ANAVAR® Brand of Oxandrolone, For Protein Tissue Building and Anabolism," 16 pages with a 5 page insert
	FDA approved Physician's Product Brochure No. 43 for ANAVAR® Brand of Oxandrolone, including Package Insert, G.D. Searle (1964)
	Fox et al., (1962), "Oxandrolone: A Potent Anabolic Steroid of Novel Chemical Configuration," J. Clin. Endocrinol. Metab., Vol. 22, pp. 921-924
	Garlick et al., (October 1988), "Regulation of Muscle Protein Turnover: Possible Implications For Modifying the Responses to Trauma and Nutrient Intake," in Bailliere's Clinical Gastroenterology, Bailliere Tindall, London/Philadelphia/ Sydney/Tokyo/Toronto, Burns ed., Vol. 2, No. 4, pp. 915-940
	Gold, E.M., Clinical Investigator's Report, May 31, 1962
	Gonzales, M.F., Olney, R.K., So, Y.T., Greco, C.M., et al. (1988). Subacute structural myopathy associated with human immunodeficiency virus infection. Arch. Neurol. 45:585-587
	Gorard, D.A., Henry, K., and Guiloff, R.J. (1988). Necrotizing myopathy and zidovudine. Lancet. 1:1050-1051
	Haupt et al., (1984), "Anabolic Steroids: A Review of the Literature," The American Journal of Sports Medicine, Vol. 12, No. 6, pp. 469-484
	Heller, C.G., Clinical Investigator's Report, June 20, 1962
	Hellerstein, M.K., J. Mudie, H. and Viteri, F. (1990). Current Approach to the treatment of human immunodeficiency virus-associated weight loss: pathophysiologic considerations and emerging management strategies. Sem. Oncol. 17:17-33
	Hernon et al., (June 1987), "Treatment of Burns," in Current Problems in Surgery, Year Book Medical Publishers, Inc., Chicago, Ravitch et al., eds., Vol. 24, No. 6, pp. 347-397
	Hughes, B.J. and Kreig, M. (1988). Steroid receptors and the muscular system. In, Steroid Receptors and Disease, Sheridan, P.J. Blum, K. and Trachtenberg, M.C. (eds). Marcel Dekker, Inc., New York, pp. 415-433
	Jones, R.W.A., El Bishti, M.M., Bloom, S.R., Burke, J., Carter, J.E., et al (1980). The effects of anabolic steroids on growth, body composition, and metabolism in boys with chronic renal failure on regular hemodialysis. J. Pediat. 97:559-566
	Karim et al., (1973), "Oxandrolone Disposition and Metabolism In Man," Clin. Pharmacol. Ther. Vol. 14, No. 5, pp. 862-869
	Kasler, M.H., Clinical Investigator's Report, March 16, 1962
SW	Kotler, D.P., Wang, J. and Pierson, R.N. (1985). Body composition studies in patients with acquired immunodeficiency syndrome. Am. J. Clin. Nutr. 42:1255-1265

EXAMINER

S. Wang

DATE CONSIDERED

1/3/06

*EXAMINER: Initial if citation considered whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
44657-AAA-PCT-USSerial No.
10/052,961INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)Applicant:
Joseph R. BergerFiling Date
January 18, 2002

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation
					Yes No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SW	Kotler, D.P., Tierney, A.R., Wang, J., and Pierson, R.N. (1989). Magnitude of body-cell-mass depletion and the timing of death wasting in AIDS. Am. J. Clin. Nutr. 50:444-447
	Kowalewski and Heron, (1970), "Effect of Thermal Injury on Excretion of Hydroxyproline In Rats, Treated Or Not With An Anabolic Androgen," Acta Endocrinologica, Vol. 64, pp. 541-547
	Leevy, C.M., Clinical Investigator's Report, August 24, 1961
	Marmo et al., (February 1974), "Experimental Analysis of Some Pharmacodynamic Effects Nor-19-Androstenedione Undecylate," Gazzetta Medica Italiana, (in Italian with English Translation), Vol. 133, No. 2, pp. 47-56
	Masse, R.B.H., Ayotte, C. and Dugal, R. (1989). Studies on anabolic steroids II - Gas chromatographic/mass spectrometric characterization of oxandrolone urinary metabolites in man. Biomed. Environ. Mass Spectrom. (England) 18:429-438
	Mendenhall, C.L., Anderson, S., Garcia-Pont, P., Goldberg, S., et al. (1984). Short-term and long-term survival in patients with alcoholic hepatitis treated with oxandrolone and prednisolone. N. Eng. J. Med. 311:1464-1470
	Mendenhall, C.L., Grossman, C.J., Roselle, G.A., et al. (1990). Anabolic steroids effects on immune function: differences between analogues. J. Steroid Biochem. Molec. Biol. 37:71-76, (Exhibit 42);
	Mensch, M., Clinical Investigator's Report, August 23, 1962
	Metcalfe, W., Clinical Investigator's Report, July 14, 1961
	Meyers, F.H., Jawetz, E. and Goldfien, A. (1980). Review of Medical Pharmacology. California: Lange Medical Publications, p. 415
	O'Shea et al., (December 1970), "Biochemical and Physical Effects of An Anabolic Steroid In Competitive Swimmers and Weightlifters," Nutrition Report International, Vol. 2, No. 6, pp. 351-361
	Pan, C.S., Inadomi, D.W., Laidlaw, S.A., Jones, M.R., and Kopple, J.D. (1984). Oxandrolone enhances muscle protein synthesis in acutely uremic rats. Kidney Intl. 25:236
	Paulsen, C.A., Clinical Investigator's Report, March 9, 1962
	Physicians' Desk Reference, (1984), 38th Edition, Huff et al. eds., pp. 1840-1841
	Roubenoff and Kehayias, (June 1991), "The Meaning and Measurement of Lean Body Mass," Nutrition Reviews, Vol. 49, No. 6, pp. 163-175
	Ruffin, J.M., Clinical Investigator's Report, March 20, 1962
	Selye, (1970), "Prevention of Indomethacin-Induced Intestinal Ulcers by Various Catatoxic Steroids," Exp. Med. Surg., Vol. 28, pp. 169-78
	Simpson, D.M. and Bender, A.N. (1988). Human immunodeficiency virus-associated myopathy: analysis of 11 patients. Ann. Neurol. 24:79-84
	Solymoss et al., (1971), "Protection by Spironolactone and Oxandrolone Against Chronic Digitoxin or Indomethacin Intoxication," Toxicol. Appl. Pharmacol., Vol. 18, pp. 586-92
SW	Stern, R., and Gold, J. and DiCarlo, E.F. (1987). Myopathy complicating the acquired immune deficiency syndrome. Muscle Nerve. 10:318-322

EXAMINER

S. Wang

DATE CONSIDERED

1/3/06

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
4657-AAA-PCT-USSerial No.
Not Yet KnownApplicant
Joseph R. BergerFiling Date
Herewith

Group

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
SW	0 2 2 2 3 8 5	February 3, 1993	Europe				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SW	Chicago Tribune, September 20, 1991, North Sports Final edition, Business Section, page 1
	Martindale, The Extra Pharmacopoeia, The Pharmaceutical Press, London, Reynolds, et al., Eds., p.1430 (1982)
	Physicians' Desk Reference (1988), 42 nd Edition, cover page and pages 1975-1976
	PR Newswire, 0828P8715, August 28, 1991 "Gynex obtains international rights to drug to treat for growth disorders, AIDS"
	Aroonsakul, Chemical Abstracts, Vol. 115: 151902q, 1988
	Lone, et al., Chemical Abstracts, Vol. 107: 174950c, 1987
	Endo, Chemical Abstracts, Vol. 73: 95098g, 1970
	Boris, et al., Chemical Abstracts, Vol. 74: 72305d, 1971
	O'Shea, et al., Chemical Abstracts, Vol. 74: 75106a, 1971
SW	Kopera, H. Acta Endocrinologica 1985, Supplementum 271, pp. 11-18

EXAMINER

S. Wang

DATE CONSIDERED

1/3/06

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant: Joseph R. Berger
U.S. Serial No.: 10/052,961
Filed: January 18, 2002
Exhibit B

